

Serial Number 10/673,650

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**REMARKS**

In view of the preceding amendments and the following remarks, Applicants respectfully request the Examiner to reconsider the patent application identified above and withdraw the present rejection. Claims 1-10 are pending in the present application, all of which stand currently rejected.

**Drawings:**

The Examiner objected to the drawings under 37 C.F.R. §1.83(a). Applicants have removed from Claim 2 the following phrase:

“; the balloon in an initial configuration being deflated, pleated and wrapped around the catheter shaft”.

The Examiner objected to the drawings under 37 C.F.R. §1.84(p)(5). Regarding reference numeral 46. Applicants have removed reference numeral 46.

**Specification:**

The Examiner objected to the disclosure, regarding informalities. Applicants have added the word “to” on page 4, line 19, and clarified that the “distal portion” on Page 9, line 4, refers to a distal portion of the hypotube.

**Claim Objections:**

The Examiner objected to the Specification regarding antecedent basis for the claimed subject matter.

First, the Examiner was unable to find a description in the specification of “the proximal end of the inner tubular body and the proximal end of the outer tubular body as being affixed together.” The transition seal is described on page 5, lines 3-8 of the present application as filed:

Serial Number 10/673,650

The hypotube defines a transition point at a distal end of the indented tubing portion, and at a proximal end of the distal portion. At or near this transition, *the proximal ends of the inner and outer tubular bodies are sealed to the hypotube*. At this transition seal, the proximal end of the inner tubular body may be partially received within a distal portion of the longitudinal indentation of the hypotube, and the outer tubular body proximal end surrounds and is sealed to both the inner body and the hypotube.

The transition seal is also described on page 8, lines 2-8 of the present application as filed:

A transition point is 44 defined on the hypotube 34 at a distal end of the longitudinally indented intermediate tubular portion 38, and at a proximal end of the distal portion 42 of the hypotube. The longitudinal position of this transition is indicated in Figure 4 as location C. At or near this transition 44, *the proximal ends of the inner and outer tubular bodies 22 and 24 are sealed to the hypotube 34*. At this transition seal, the proximal end of the inner tubular body 22 is partially received within a distal portion of the longitudinal indentation 40 of the hypotube 34.

The transition seal is also described on page 9, lines 6-8 of the present application as filed:

Another reason the present invention improve cost-effectiveness of manufacturing is that only *one intermediate shaft seal* is needed, rather than a separate seal of hypotube to polymer tube and a seal at the proximal guidewire port.

The transition seal is also shown in the center of Figures 2 and 22.

Second, the Examiner was unable to find a description in the specification of the "balloon in an initial configuration being deflated, pleated and wrapped". This text was present in Claim 2 of the present application as filed, so it is included in the description of the initial disclosure. However, Applicants have canceled it from Claim 2.

Third, the Examiner was unable to find a description in the specification of what is meant by "a single seal". The single seal is the transition seal mentioned above and described in several places in the present application as filed, including the following on page 9, lines 6-8:

Serial Number 10/673,650

Another reason the present invention improves cost-effectiveness of manufacturing is that only *one intermediate shaft seal* is needed, rather than a separate seal of hypotube to polymer tube and a seal at the proximal guidewire port.

The Examiner also objected to Claims 1-10 regarding antecedent basis and a spelling error. Applicants have amended the Claims to clarify antecedent basis.

35 U.S.C. §112:

The Examiner rejected Claim 2 under 35 U.S.C. §112:, second paragraph, regarding antecedent basis. Applicants have amended Claim 2 to clarify antecedent basis.

35 U.S.C. §102:

The Examiner rejected Claims 1-6, 9 and 10 under 35 U.S.C. §102(b), with reference to Keith (5,217,482). However, Applicants respectfully submit that the cited references fail to teach or suggest the present invention, as recited in the claims. For example, Claim 1 includes the following limitations, among others:

a hypotube having a proximal tubular portion, an intermediate tubular portion having a longitudinal indentation, *and a distal portion;*

an inner tubular body having a proximal and distal end, and defining a proximal and distal guidewire port at each end respectively, and a guidewire lumen extending between the guidewire ports;

an outer tubular body having a proximal and distal end, and surrounding at least a portion of the inner tubular body;

the proximal ends of the inner and outer tubular bodies being affixed together and sealed to the hypotube at a point defined at or near a transition between the intermediate and distal portions of the hypotube;

\* \* \*

an inflation lumen extending from a proximal end of the hypotube, through the hypotube proximal and intermediate tubular portions, and through an annular space between the outer and inner tubular bodies, into an interior of the balloon;

Serial Number 10/673,650

*the distal portion of the hypotube extending a distance into the outer tubular body;*

*providing a transition in flexibility between the tubular portions of the hypotube to the inner and outer bodies;*

the balloon catheter thus having a rapid-exchange configuration.

With particular reference to the Keith reference, item 74B is both tubular and indented, as is indicated in Figure 3 of the Keith reference. Accordingly, it fails to teach or suggest the hypotube component of the present invention, "having a proximal tubular portion, an intermediate tubular portion having a longitudinal indentation, and a distal portion" which extends "a distance into the outer tubular body; providing a transition in flexibility between the tubular portions of the hypotube to the inner and outer bodies".

Indeed, it isn't possible for item 74B of the Keith reference to provide a "transition in flexibility between the tubular portions of the hypotube to the inner and outer bodies", because item 74B is itself a "tubular portion" of the hypotube. This is bolstered by the fact that in the Keith reference, another component provides such a "transition in flexibility between the tubular portions of the hypotube to the inner and outer bodies", and that component is "coil member 212 of the kink-resistant structure 210". In contrast, the novel hypotube component of the present invention obviates such a flexibility transition component.

35 U.S.C. §103:

The Examiner rejected Claims 7 and 8 under 35 U.S.C. §103(a) over Keith in view of Reeseemann (5,425,711). Applicants respectfully submit that the cited references fail to teach or suggest the present invention as recited in the Claims, for the reasons set forth above.

Accordingly, Applicants respectfully request the Examiner to allow the present invention.

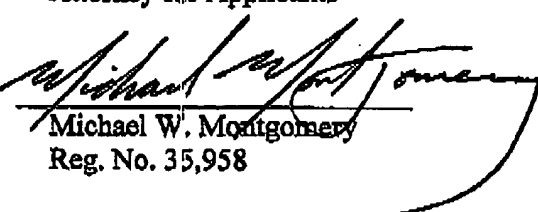
Serial Number 10/673,650

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